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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,001	09/26/2005	Medasani Munisekhar	VISH0101PUSA	1418

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EXAMINER
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CHEN, CATHERYNE

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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04/20/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,001	<b>Applicant(s)</b> MUNISEKHAR, MEDASANI	
	<b>Examiner</b> CATHERYNE CHEN	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16, 18-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 18-26, 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Amendments filed on Jan. 19, 2010 has been received and entered.

Currently, Claims 16, 18-26, and 28-30 are pending and examined on the merits.

Claims 1-15, 17, and 27 are canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration of Biotrail Pharma Services Limited filed Jan. 19, 2010 has been considered.

### ***Election/Restrictions***

Applicant's election without traverse of the species ammonium chloride, keratolytic composition, psoriasis, benzalkonium chloride in the reply filed on Oct. 23, 2008 is acknowledged.

### ***Response to Arguments***

### ***Claim Rejections - 35 USC § 103***

Claims 16, 18-26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEleney et al. (US 5680962), Durr et al. (US 5997889), McAtee et

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al. (US 5607980) and further in view of Knoll et al. (US 4822604) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

McEleney et al. teaches a lotion with pH 6.5 or less (column 3, lines 11-13) for topical use (column 3, line 37), with cationic chloride (column 6, line 41), quaternaries such as alkylbenzyltrimethylammonium salts, heterocyclic ammonium salts (column 7, lines 11-12), and perfumes to impart desired fragrance such as vanilla (column 8, lines 64), for formulation into creams, lotions, sticks, gels, oils, and mousses (column 10, lines 1-2). Benzalkonium chloride is also known as alkyltrimethylbenzylammonium chloride. Vanilla is the whole plant.

However, it does not teach the amounts of vanilla from about 0.1% to an amount less than 2% by weight, amount from about 0.001% to about 40% by weight of quaternary ammonium, amount from about 0.001% to about 10% by weight of ammonium chloride, and psoriasis.

Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7).

As for concentration of vanilla, Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract).

As for concentrations of quaternary ammonium and cation chloride salt, McAtee et al. teaches a topical composition comprising from about 0.1-15% by weight of a cationic surfactant (Claim 1). Cationic surfactant can be stearamidopropyl dimethyl ammonium chloride (column 8, lines 33, 43-44) and quaternary ammonium salt cetyl ammonium chloride (column 8, lines 46, 48). The composition can be formulated into creams, lotions, mousses, sprays, cleansers, bars, gels, and the like (column 4, lines 4-7). Psoriasis is a skin problem with disorders of keratinization; therefore, there is need for topical skin care composition which give skin smooth and elegant feel (column 1, lines 38-40, 53-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the solutions to treat psoriasis because Durr et al. teaches lotions with vanilla extract can be used to treat psoriasis. One would have been motivated to make use lotions with vanilla extract for the expected benefit of treating psoriasis. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use ammonium chloride because Knoll et al. teaches lotions with ammonium chloride can be used to treat psoriasis. One would have been motivated to make use lotions with ammonium chloride for the expected benefit of treating psoriasis. Absent evidence to the contrary, there would have been a reasonable expectation of

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success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising vanilla from about 0.1% to an amount less than 2% by weight, amount from about 0.001% to about 40% by weight of quaternary ammonium, amount from about 0.001% to about 10% by weight of ammonium chloride combination for the following reasons. The references do teach the composition for treating topical skin and psoriasis. Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7). As for concentration of vanilla, Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract). As for concentrations of quaternary ammonium and cation chloride salt, McAtee et al. teaches a topical composition comprising from about 0.1-15% by weight of a cationic surfactant (Claim 1). Thus, it would have been obvious to make a concentrated composition containing vanilla extract, quaternary ammonium, and ammonium chloride for use as a topical agent to treat psoriasis. Additionally, the amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general

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conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, especially within the ranges taught by the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant argues that McEleney et al. does not teach treatment for psoriasis.

In response to Applicant's argument, Applicant's claim is drawn toward a treatment for skin disorder, McEleney et al. teaches ingredients for topical use to treat sunburn (column 1, lines 14-22), which is a skin disorder. Topical creams are applicable to skin, which is the situs for psoriasis. As for treatment of psoriasis, Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7). Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract). McAtee et al. teaches a topical composition comprising from about 0.1-15% by weight of a cationic surfactant (Claim 1). Cationic surfactant can be stearamidopropyl dimethyl ammonium

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chloride (column 8, lines 33, 43-44) and quaternary ammonium salt cetyl ammonium chloride (column 8, lines 46, 48). The composition can be formulated into creams, lotions, mousses, sprays, cleansers, bars, gels, and the like (column 4, lines 4-7).

Psoriasis is a skin problem with disorders of keratinization; therefore, there is need for topical skin care composition which give skin smooth and elegant feel (column 1, lines 38-40, 53-55). Thus, an artisan of ordinary skill would reasonably expect that agents for psoriasis could be used as the types of ingredients for topical skin taught by the references. This reasonable expectation of success would motivate the artisan to use vanilla extract, quaternary ammonium, and ammonium chloride in the reference composition. Thus, using the ingredients for treating psoriasis is considered an obvious modification of the references.

Applicant argues that there is picking and choosing of ammonium chloride.

In response to Applicant's argument, while the reference might not teach a specific embodiment with the claimed ingredients, the reference does list these ingredients as being appropriate for combination into a topical lotions used for performing health. As discussed in *KSR International Co. v. Teleflex Inc.*, 550 U.S.--, 82 USPQ2d 1385 (2007) it is considered obvious to combine prior art elements known to be used in equivalent fields of endeavor together into a single combination. The reference clearly shows that the claimed ingredients were known to be used in equivalent fields of endeavor; thus, it is considered obvious to combine them together.

Applicant argues that there is unexpected result.

In response to Applicant's argument, the declaration of Biotrail Pharma Services Limited shows results for treating psoriasis and the specific amounts for the ingredients are not found. The results are not commensurate in scope with the claims. Therefore, the results are not convincing for unexpected results.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen  
Examiner Art Unit 1655

/Michele Flood/

Primary Examiner, Art Unit 1655